K090350

Innovation In Motion
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510(k) Summary
Extreme 4x4-X8 Power Wheelchair
Innovation In Motion
510(k) Premarket Notification

APR 10 2009

Applicant's Name, Address, Telephone, Fax, and E-mail information:

Innovation In Motion
201 Growth Parkway
PO Box 507
Angola, IN 46703
Phone: 260.665.2769
Fax: 260.665.3047
E-mail: rick@vestil.com

Preparer's Name, Address, Telephone, Fax, Contact Name, E-mail information, and Date Prepared:

Innovation In Motion
201 Growth Parkway
PO Box 507
Angola, IN 46703
Phone: 260.665.2769
Fax: 260.665.3047
Contact Name: Rick Michael
Vice President
E-mail: rick@vestil.com
Date: February 2009

Manufacturer's Name, Address, Telephone, and Fax Information:

Magic International Pty. Ltd.
2/16 Viewtech Place
Rowville, Victoria 3178
Australia
Phone: 011.613.9755.8100
Fax: 011.613.9755.8111

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Device Trade, Common, and Classification names:

Device Name: Extreme 4x4- X8

Common Name: Power Wheelchair

Classification Name: Restorative Devices

Predicate Device:

Extreme 4x4- X4 (K000796)

Device Description:

The Extreme 4x4- X8 is a battery powered, electric motor driven device with the intended function of providing mobility to persons limited to a sitting position, that have the capability of operating a powered wheelchair. It is a four-wheel drive format wheelchair as its basic configuration with direct drive motors on all four wheels. The wheelchair frame is a non-folding type.

The frame of the unit is of welded steel construction. The wheelchair consists of the following basic components: frame w/four motors, joystick, seat, armrests, and footrests.

Intended Use:

This device is an electric powered wheelchair for indoor and/or outdoor use, to be used by partially disabled individuals capable of operating a few essential hand controls.

Device Comparison Table:

COMPARISON TABLE WITH MARKETED DEVICE

K000796 ~~K000796~~

	X4	X8
Type	Wheelchair, Power	Wheelchair, Power
Intended Use	To provide mobility to persons limited to a sitting position, who have the capability of operating a power wheelchair	To provide mobility to persons limited to a sitting position, who have the capability of operating a power wheelchair
Where Used	Designed to operate indoors and over a variety of outdoor surfaces including soft/rough terrain with inclines up to 1 in 14	Designed to operate indoors and over a variety of outdoor surfaces including soft/rough terrain with inclines up to 1 in 14
Design	Compact, rigid	Compact, with front frame articulation
Construction	Steel frame	Steel frame
Dimensions	Overall length: 43.3" Overall width: 28"	Overall length: 45.25" Overall width: 28"
Wheel Size	4 x Ø14"	4 x Ø14"
Rolling Base Weight (No Seat, No Batteries)	159 lbs.	145 lbs.
Range	19 miles	25 miles
Maximum Speed	5 mph	6.5 mph
Maximum Weight Capacity	400 lbs	400lbs
Controller	Dynamic DX-PMB2 electronic control and joystick *Programmable to meet individual needs *Battery charge level gauge *Attaches to either side	Dynamic DX2-PMA70L electronic control and joystick *Programmable to meet individual needs *Battery charge level gauge *Attaches to either side
Motors	Four 24V, 4 pole direct drive motors/gearbox *Freewheeling lever/motor lock releases and engages front and rear motor brakes	Four 24V, 4 pole direct drive gear in line motors/gearbox *Freewheeling lever/motor lock releases and engages rear motor brakes
Suspension	None	None
Batteries	Two 73 Amp/hour	Two 73 Amp/hour
Seat Width	16"-24"	16"-24"
Seating	Upholstery meets California 117 specifications for fire retardancy	Upholstery meets California 117 specifications for fire retardancy
Footrest	1 piece rigid footplate, flip up footplates and others	1 or 2 piece, fixed or flip up, angle and height adjustable rigid footplates, and others
Armrest	Height adjustable, removable	Height adjustable, removable
Safety Features	Electromagnetic brake engaged when chair is stationary. When electromagnetic brakes are disengaged, chair cannot be driven	Electromagnetic brake engaged when chair is stationary. When electromagnetic brakes are disengaged, chair cannot be driven Drive is inhibited with some seat positioning functions

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Substantial Equivalence:

The X8 has the same intended function and use as the X4. The X8 is the next generation of the X4 with minor modifications:

- Articulated frame for improved obstacle climbing and handling
- High Speed, high torque high efficiency gear in-line motors
- Latest edition of Dynamic Control electronic software/hardware

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 10 2009

Vestil Manufacturing Coporation
% Innovation in Motion
Mr. Rick Michael
Vice President
201 Growth Parkway
Angola, Indiana 46703

Re: K090350

Trade Name: Extreme 4x4 – X8
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered wheelchair
Regulatory Class: II
Product Code: ITI
Dated: March 16, 2009
Received: March 20, 2009

Dear Mr. Michael:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

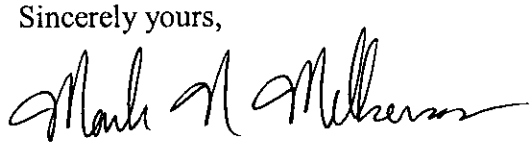
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: EXTREME 4x4 - XB

Indications For Use:

The intended use of the XB power wheelchair is to provide mobility to persons limited to a sitting position, who have the capability of operating a power wheelchair.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N Milhorn

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K090350